

REMARKS

In paragraph 3 of the Office Action, claims 36-42 were rejected under 35 U.S.C. §103(a) over Dorigatti et al. (Dorigatti).

Reconsideration is requested.

Dorigatti discloses hyaluronic acid (HA) total or partial esters having different esterification degrees that are to be processed in the form of non-woven fabrics. These non-woven fabrics are intended for use in the medical/pharmaceutical field as skin coverings or as buffer media in surgery of nose and inner ear.

Examples 1-26 of Dorigatti relate both to the preparation of HA total esters and of HA partial esters. In particular, Examples 12 and 14 disclose the preparation of the HA total benzyl ester.

Examples 27-31 of Dorigatti relate to non-woven fabrics made of partial or total esters. In particular, Examples 27 and 31 relate to non-woven fabrics made of HA total benzyl ester and Example 29 refers to a non-woven fabric made of HA total benzyl ester mixed with HA total ethyl ester, and Example 30 refers to a non woven fabric made of HA total benzyl ester mixed with HA partial benzyl ester with esterification degree of 75% in a proportion of 1:1, so that the degree of esterification of the resulting product is 87.5%.

The present invention, as pointed out by the amended claims, is concerned with the use of a HA partial benzyl ester having an esterification degree of 65%. this amendment is supported by the original disclosure, particularly at page 9, line 4.

The Examples of Dorigatti fail to disclose the partial benzyl ester of HA as pointed out in the amended claims and moreover there is no teaching that a 65% benzyl ester of HA has special advantages as compared to other partial benzyl esters of HA. The 65% benzyl ester of HA is novel as it is not disclosed nor suggested by Dorigatti wherein the total benzyl ester of HA was prepared in Examples 12 and 14, and a non-woven fabric made of HA total benzyl ester or of HA partial benzyl ester with an

esterification degree of 87.5% was disclosed in Examples 27 and 29-31.

As a matter of fact, the teaching of Dorigatti was to use HA benzyl esters, which were totally esterified or have a very high degree of esterification.

Therefore, a worker in the art who was aware of Dorigatti would have not had any incentive to make non-woven fabrics with HA partial benzyl esters having an esterification degree of 65%. The only examples of Dorigatti, wherein HA partial esters having a lower esterification degree are disclosed, are Examples 1, 2 and 8 respectively which disclose the propyl ester of HA, the isopropyl ester of HA and the butyl ester of HA, i.e. HA esters with aliphatic alcohols which are completely different from the present benzyl alcohol. Furthermore, these 50% esterified HA derivatives have the remaining 50% of carboxylic groups sallified with a metal, thus being completely different chemical compounds from the presently claimed benzyl ester of HA which has 65% of the carboxy groups esterified with benzyl alcohol and 35% of free carboxy groups.

The experimental data of record proves that the HA benzyl esters processed in the form of non-woven tissue and with an esterification degree of 65%, induce a higher re-epithelialization and a greater degree of bone regeneration than the total benzyl esters of HA made in the same form. The results of these experiments are illustrated in the Drawings 1-3 as originally filed.

The data in Drawing 1 shows that the percentage of newly formed bone is markedly higher when the benzyl ester of HA (HYAFF 11p65) having a degree of esterification of 65% is used as compared to the case when the material is made of the corresponding total ester (HYAFF 11) prepared according to Examples 12, 14, 27, 29 and 31 of Dorigatti. In the Drawing 2, the percentage of re-epithelialization is illustrated for the presently claimed non-woven tissue made of HYAFF 11p65 in comparison with the corresponding HA derivative totally esterified HYAFF 11 of Dorigatti and the superiority of the first one is evident also in this case.

In conclusion, even if Dorigatti mention the possible use of HA esters as buffer media in surgery involving the nose and inner ear or as skin coverings, this does not make obvious the preparation of the present benzyl ester having a specific degree of esterification of 65%.

The Applicant has surprisingly found that the esterification of 65% of the carboxy groups of HA gives the best results in regenerating tissues. In the absence of any teaching of this result in the prior art, the subject matter of the amended claims cannot be deemed to be obvious.

An early and favorable action is earnestly solicited.

Respectfully submitted,

  
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